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Error Reduction and Prevention in Surgical Pathology

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Disclosure

- None

Course Objectives

- At the end of the presentation participants should be able to:
  - Identify where errors occur within the test cycle
  - Implement effective methods to help detect and prevent errors
  - Apply general principles of error reduction to enhance the overall quality of surgical pathology

Agenda

- Source, frequency and significance of errors
- General principles of error reduction
- Identification (pre-analytic) errors
- Diagnostic (analytic) error
- Post-analytic errors

Error Rates

	# of Cases	Case Selection	Error Rate(%)	Sig. Error Rate(%)
Safrin & Bark, 1993	5,397	Consecutive	0.5	0.26
Whitehead, 1985	3,000	Consecutive	7.8	0.96
Lind, 1995	2,694	Diagnostic Bx	13	1.2
Lind, 1995	480	Random	12	1.7
Renshaw, 2003	11,683		0.0 - 2.36	0.34 - 1.19
Raab, 2008	7,444 380	5% Random Focused	2.6 13.2	0.36 3.2

Error Rates
Inter-institutional review

	Error Rate (%)	Significant Error Rate (%)
Kronz, 1999	N/A	1.4
Abt, 1995	7.8	5.8
Gupta, 2000	1—30	2—5
Malhotra, 1996	11.6	N/A
Weir, 2001	6.8	3.7
Tsung, 2004	11.1	5.9
Swapp, 2012	5.4	0.6

Errors in Surgical Pathology

- Pre-analytic
  - Wrong identification: 27-38%
  - Defective specimens: 4-10%
- Analytic
  - Diagnostic mis-interpretation: 23-29%
- Post-analytic
  - Defective report: 29-44%
- Am J Clin Pathol 2008;130:238-246

The Doctors Company

- Am J Surg Pathol 2004;28:1092-1095
- 272 surgical pathology claims (1998-2003)
- 166 (61%) false negative
- 73 (27%) false positive → Analytic
- 10 (4%) frozen section
- 22 (8%) operational
  - 13 mix-ups → Pre-analytic
  - 3 floaters → Analytic
  - 2 mislabeled biopsy site → Post-analytic
  - One transcription error, “no” omitted before malignant cells

171 Jury Verdict and Settlements

- **Arch Pathol Lab Med. 2007;131:615-618**
- **LexisNexis search**

	Surgical Pathology	Cytology	Clinical Pathology
1988-1993	26	9	16
1994-1999	25	20	14
2000-2005	33	19	9
Total	84 (49%)	48 (28%)	39 (23%)

Surgical Pathology Cases

- False negative, 73% ← Analytic
- False positive, 19%
- System errors, 8% ← Pre-analytic
  - 4 lost or mixed-up specimens
  - 2 floaters lead to false positive
  - 1 no communication of lack of chorionic villi in POC leading to ruptured tube

Post-analytic

Risk

- Pre-analytic
  - Specimen identification
  - Clinical information
- Analytic
  - Diagnostic accuracy
- Post-analytic
  - Report completeness
  - Communication of significant results

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Specific Factors That Lead to Errors

- Hand-offs
  - Weak links
- Complexity
  - Risk of error increases with every step
- Inconsistency
  - Level of training, performance, procedures, communication, language or taxonomy

Specific Factors That Lead to Errors

- Human intervention
  - Machines are better at routine tasks
  - Humans are better in unexpected conditions
- Time constraints
  - Forces compromise
- Inflexible hierarchical culture

General Error Reduction Methods

- Standardize all procedures
- Remove distractions
  - Accessioning, grossing, cutting, microscope, sign-out
  - Make people aware of this potential
- Automate where possible
  - Specimen handling, analyzers
  - Comprehensive computer systems

General Error Reduction Methods

- Remove inconsistent tools
  - Handwriting
- Reduce complexity
  - Automation
  - Lean design
- Make everyone aware of hand-offs (problem points)
- Reduce reliance on memory
  - Checklists

General Error Reduction Methods

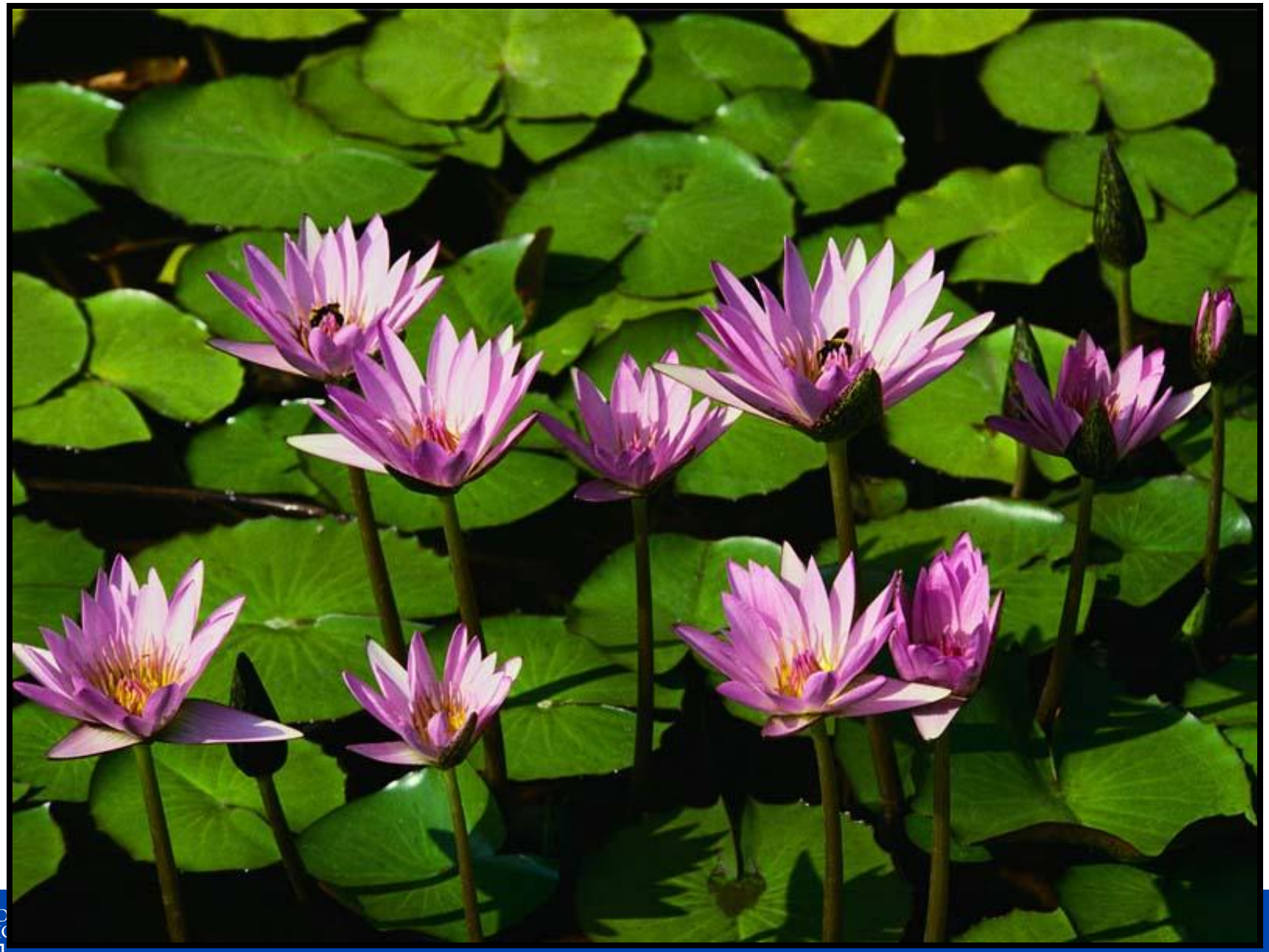
- Enhance communication
  - Electronic medical record
  - Computer physician order entry (CPOE)
- Adequate and appropriate staffing
  - Batch work
  - Redundancy
  - Suitability
- Adequate and appropriate facilities
  - Space, lighting
- Reduce the stress level

General Principles of Error Reduction

- Sustained error reduction generally comes with a comprehensive persistent effort
- Unlikely to succeed with one intervention
- Continuously examine and redesign systems
- Build-in prevention and detection systems through QA and QC measures

General Principles of Error Reduction

- Continuously monitor and analyze QA and QC data
- Intervene at the earliest sign of variations
- Share quality assurance data
- Communicate to all workers that their work matters to patients



Pre-analytic Errors

- **Specimen identification**
- Specimen collection
- Specimen labeling
- Specimen fixation
- Specimen transport
- Accessioning

Specimen Identification

- Reasons for ID errors
  - Dependent of numerous individuals and locations outside the control of the laboratory
  - Inconsistent training
  - Inconsistent application of labeling standards

Specimen Identification

- CAP study of 1 million surgical specimens in 417 Laboratories
  - 6% deficiencies (Median 3.4%)
    - Specimen ID problems 9.6%
    - Information problems 77%
    - Handling problems 3.6%
    - Others 9.7%

Arch Pathol Lab Med 1996;120:227

Root Cause Analysis of VA Laboratories

- Arch Pathol Lab Med 2010;134:244-255
- 227 Root Cause Analysis Reports
- ID errors accounted for 182/253 adverse events
- 132 (73%) pre-analytic, 37 (20%) analytic, 13 (7%) post-analytic
- Mislabeling associated with “batching” (35)
- Manual entry of lab forms (14)
- Failure of 2 person verification in blood bank (20)
- 27/37 analytic relabeling of containers-blocks-specimens

Specimen Identification

- Joint Commission patient safety goal
  - Improve the accuracy of patient identification
- CAP patient safety goal
  - Improve patient and sample identification
- Mishaps have led to disastrous examples of wrong surgery or treatment

Specimen Identification

- PSG provide the muscle to be able to attack this problem
- Need to adopt specimen identification as an institutional goal (change the culture)
  - QA measure for clinics, OR, etc.
- Cannot be achieved from within the laboratory

Specimen Identification

- Sustained awareness campaign
- Change the culture
  - Extensive education and training with annual refresher sessions
  - Recent report of specimen time-out in the OR
- Strict adherence to labeling standards and labeling procedures
- Remote order entry (forcing function)
- Newer technology may be helpful
  - Recent reports of “DNA time out”
- Make everyone in the process aware of pitfalls and the possibility of misidentified specimens

Factors that Improve Performance

- Limit preprinting of labels (batch printing)
- Look for ID errors prior to release of results (QC checks)
- Investigate patient ID when not on file
- Continuously monitor ID errors
- Check report vs. requisition
- Use strict acceptance (rejection) criteria
- Arch Pathol Lab Med 2006;130:1106-1113

Improvement in Patient Identification

- 1 year, 0.8%
- 2 years, 2.7%
- 3 years, 3.8%
- 4 years, 4.1%
- 5 years, 5.6%
- 6 years, 6.2%
- Arch Pathol Lab Med 2003;126:809-815

Specimen ID

- Surgical specimen identification error: A new measure of quality in surgical care. Surgery 2007;141:450-5
- Dept of Surgery, John Hopkins
  - 21,351 surgical specimens
  - 91 surgical specimen (4.3/1000) ID errors
  - 18 not labeled
  - 16 empty containers
  - 16 laterality incorrect
  - 14 incorrect tissue site
  - 11 incorrect patient
  - 9 no patient name
  - 7 no tissue site
- 0.512% outpatient clinic, 0.346% operating rooms

Gross Room and Histology Lab

- Significant opportunity for error
- 2009 Q-Probes study in 136 labs
  - 1.1/1000 mislabeled cases
  - 1.0/1000 mislabeled specimens
  - 1.7/1000 mislabeled blocks
  - 1.1/1000 mislabeled slides

Gross Room and Histology Lab

- Error frequency
  - Before and at accessioning 33.3 %
  - Block labeling and dissection 31.9 %
  - Tissue cutting and mounting 30.4%
- Errors detected at the one or two steps immediately after the error
- Include periodic error checks throughout the system

Gross Room and Histology Lab Solutions

- Lean redesign
- Am J Clin Pathol 2009;131:468-477
  - Reduce case ID errors 62%
  - Reduce slide ID errors 95%
- Lean production – advantages
  - Eliminates procedural steps (simplification)
  - Aligns and even out workflow (eliminate batch work)
  - Judicial use of technology
    - Barcodes, readers, labelers (consistency)
  - Standardization of procedures (consistency)

Error Factors

- Factors that correlated with error
  - Pathologist
  - Specimen type (breast, gyn >>GI, Skin)
  - Diagnosis (non-dx, atypia >>neg)
  - Sub-specialization
  - # of pathologist on report
- Factors not correlated with error
  - Workload
  - Years of experience
  - Use of special stains
- Am J Clin Pathol 2007;127:144-152

Accurate Interpretive Diagnoses

- Knowledge, Experience and Training
- Standardization of Terminology and Procedures
- Clinical History and Clinical Correlation
- Ancillary Studies
- Case Reviews

Knowledge, Experience and Training

- Initial qualification
  - Medical school, residency, boards
  - JC – Focused professional practice evaluation (FPPE)
- Ongoing education and ongoing competence assessment
  - ABP four part MOC process
  - JC – Ongoing professional practice evaluation (OPPE)

Standardization of Terminology and Procedures

- Diagnostic terminology
  - Cancer diagnosis/checklists
  - Non-cancer diagnosis
    - Banff rejection grading
    - Hepatitis grade and stage
    - Etc.
- Laboratory and sign-out procedures

Standardized Diagnostic Criteria

- Breast borderline lesions
- Rosai Am J Surg Pathol 1991;15:209-21
  - 17 proliferative lesions
  - 5 pathologists with interest in breast disease
  - Each used his/her criteria
  - No agreement on any case by all 5 pathologists
  - 33% diagnoses spanned hyperplasia to CIS
  - Some pathologists consistently more benign or more malignant
  - High level of variability

Standardized Diagnostic Criteria

- Schnitt Am J Surg Pathol 1992;16:1133-43
  - 24 proliferative lesions
  - Six expert breast pathologists
  - Used the same diagnostic criteria (Page)
  - Complete agreement in 58% of cases
  - Agreement of 5 or more in 71%
  - Agreement of 4 or more in 92%
  - No pathologists was more benign or malignant than others

Standardized Diagnostic Criteria

- Use of standardized checklists
  - Increases report completeness
  - Everyone uses the same language
  - Facilitates establishment and comparison of treatment protocols
- Forces pathologists to update their knowledge
  - Motivation for ongoing educations – CME
  - Checklist – what does this mean, how do I evaluate this?

Standardization of Procedures and Terminology

- Sign out procedures
  - Use of standardized terminology
  - Use of checklist
  - Selected case reviews before sign-out
- Laboratory procedures
  - Fixation time
  - Gross room dissection and taking sections.
  - Consistent uniform processing of tissue (fixation, cutting, staining)
  - Automation (usually leads to more uniform procedures)

Clinical History and Clinical Correlation

- Understanding the clinical question
- In part why sub-specialists do better at addressing specific situations.
- Affects report completeness
- Affects diagnostic accuracy
    - R/O tumor
    - Medical disease

Clinical History

- Clinical information in surgical pathology
- 771,475 case from 341 institutions
- 2.4% of cases have no history
- 5594 (0.73%) required additional information
- 31% resulted in a delay in diagnosis
- 6.1% of cases new information lead to substantial change in diagnosis

Arch Pathol Lab Med 1999;123:615-619

Clinical History

- Study of amended reports
  - 10% additional clinical history
  - 20% clinician identifies clinicopathologic discrepancy
  - Arch Pathol Lab Med. 1998;122:303-309
- Malpractice Claims
  - 20% failure to obtain all relevant information
  - Am J Surg Pathol 1993;17:75-80

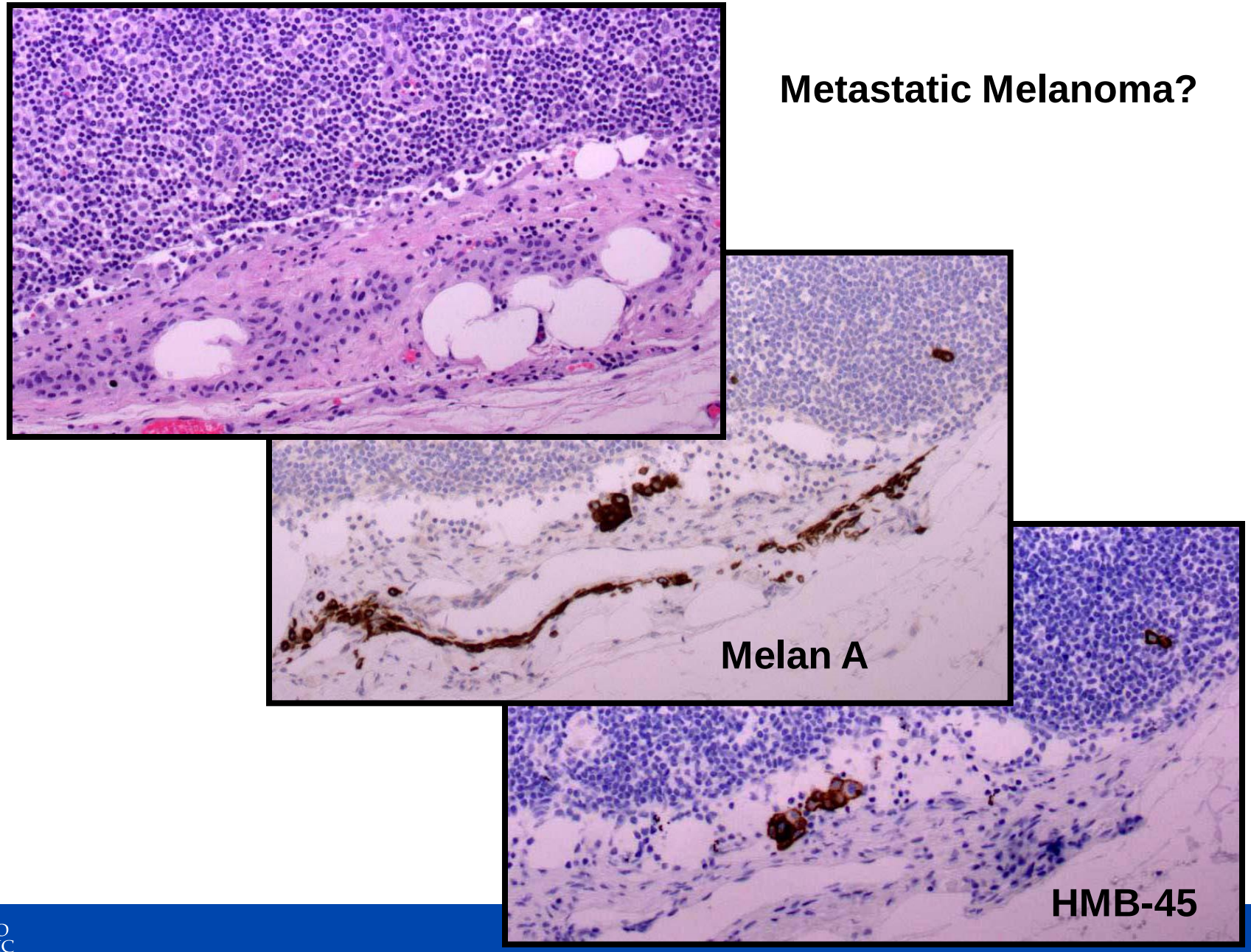
Clinical History

- Solutions
  - Electronic medical record
  - Multidisciplinary teams
  - Tumor board or other multidisciplinary conference
  - Sub-specialization

Ancillary Studies

- Mostly a blessing for pathologists
- Must work hard to maintain reliability of ancillary studies
- Complex systems requiring stringent quality control and quality assurance

Metastatic Melanoma?



Ancillary Studies

- Help determine cell lineage and diagnosis
  - Prostate specific antigen
  - HMB45, Melan A
  - TTF-1
  - Thyroglobulin
  - CD 117
- Help determine therapy
  - ER, PR, HER2
  - BRAF, KRAS, ALK, EGFR, CD117, CD20

Redundancy (Review of Cases)

- Principle method used to prevent or detect cognitive errors
- Most AP labs have limited # of specimens for double read
  - Breast, thyroid, pigmented skin lesions, Barrett's dysplasia, Brain tumors
- Taught early in training (instinctive)
- One method to keep up to date
- Problematic for small groups

Consultations

- 0.5% of all cases (median .7%, 0-2%)
  - Arch Pathol lab med 2002;126:405-412
- Less in larger groups
  - Presence of experts on staff
- ASCP guidelines
  - Am J Clin Pathol 2000;114:329-335
  - Problem prone case
  - Defined by the individual, group, clinician, patient or literature

Frequency of Routine Second Opinion

- Benign diagnosis
  - Breast 6%
  - Prostate 18%
  - Nevi 8%
- Malignant diagnosis
  - Breast CA on needle Bx 42%
  - Prostate CA on needle Bx 43%
  - Melanoma 58%
  - GI CA on biopsy 34%

Unpublished data (2001) from PIP program

Routine Review Before Sign-out

- CAP 2008 Q-Probes study
  - Archives Pathol Lab Med 2010;134:740-743
- 45 Laboratories, 18,032 cases
- 6.6% (median 8.2%) had review before sign-out
- 78% reviewed by one additional pathologist.
- 46% for a difficult diagnosis
- 43% per departmental policy

Routine Review Before Sign-out

- 45% malignant neoplasm
- Most common organ systems
  - GI 20%, breast 16%, skin 13%, GYN 10%
- Labs with review policy
  - Higher review rates (9.6% vs. 6.5%)
  - Reviewed a higher % of malignancies (48% vs. 36%)

Routine Second Opinion

- 13% of case were seen by >1 pathologist
- Disagreement rate 4.8% vs. 6.9%, P=.004
- Amended report rate 0.0 vs. 0.5%
- Best selection of case to be reviewed remains unknown

Am J Clin Pathol 2006;125:737-739

Routine Second Opinion

- Comparison of rates of misdiagnoses over two one year periods
  - Without routine second review
  - With routine second review
- Results
  - 10 misdiagnoses without review out of 7909 cases (1.3%)
  - 5 misdiagnoses with review out of 8469 cases (0.6%)

Pathology Case Review 2005;10:63-67

Routine Second Opinion

- Study of amended reports
- 1.7 million cases in 359 labs
- 1.6/1000 amended report reviewed after sign-out
- 1.2/1000 amended reports reviewed before sign-out
- Arch Pathol Lab Med. 1998;122:303-309

Pre-Sign out Quality Assurance Tool

- Am J Surg Pathol 2010;34:1319-1323
- Randomly selects an adjustable % of case for review by a second pathologist
- Disagreements similar to retrospective reviews
- TAT slightly shorter (P=0.07)
- Amended reports decreased by 30%
- Amended reports for diagnostic edit decreased 55%

Method of Review (Renshaw and Gould)

- Tissue with highest amended rates: Breast 4.4%, endocrine 4%, GYN 1.8%, cytology 1.3%
- Specimen types with highest amended rates: Breast core bx 4.0%, Endometrial curettings 2.1%
- Diagnoses with highest amended rates: nondx 5%, atypical/suspicious 2.2%
- Am J Clin Pathol 2006;126:736-7.39

Method of Review (Renshaw and Gould)

- Reviewing nondiagnostic and atypical /suspicious – review 4% of cases and detect 14% of amended reports
- Reviewing all breast, GYN, non-GYN cytology and endocrine material – review 26.9% of cases and detected 88% of amended reports.

Method of Review (Raab et al)

- Targeted 5% random review vs. focused review
- 5% random review – 195/7444 cases (2.6%)
- Focused review 50/380 cases (13.2%)
- Thyroid gland (pilot), GI, bone and soft tissue, GU
- P<.001
- Major errors: Random 27(0.36%) vs. Focused 12 (3.2%)
- Am J Clin Pathol 2008;130:905-912

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Post-Analytic Risk

- Complete reports
- Effective and timely communication of important results

Post-analytic

- Complete reporting
  - Evidence based medicine: oncology
  - Commission on Cancer of the American College of Surgeons
    - *Cancer Program Standards 2004*
    - 90% of cancer reports must have required elements based on the CAP's publication *Reporting on Cancer Specimens*
    - Summary checklists

Post-analytic

- Branston et al. European J Cancer 38;764:2002
  - Randomized controlled trial of computer form-based reports
  - 16 hospitals in Wales
  - 1044 study , 998 control
  - 28.4% increase in report completeness
  - Acceptable by pathologist
  - Preferred by clinicians

Critical Value Policies

- Based on regulatory mandates all institutions have critical value policies
- Policies apply to clinical pathology, radiology and other areas where testing is done (cardiology, respiratory therapy, etc)
- Policies typically mandate that result is reported within a specified timeframe (usually 30 or 60 min)
- Clinical Labs report >95% within 30 min

Effective Communication of Important Results

- Regulatory mandates
- CLIA 88
  - **immediately alert … an imminent life- threatening condition, or panic or alert values**
- Joint Commission
  - develop written procedures for managing the critical results,
  - define CR,
  - by whom and to whom,
  - acceptable time
- LAP
  - There is a policy regarding the communication, and documentation thereof, of significant and unexpected surgical pathology findings

Surgical Pathology and Cytology

- Tissue processing takes hours and up to a day to complete – Why 30-60 min to report?
- ?? Critical – most diagnoses are important for treatment but not imminently life threatening
- Poor agreement among pathologists and clinicians
- Most reported cases of patient harm related to communication problems are due to lack of communication or missed communication not delay

Pereira et al AJCP 2008;130:731

- Do you believe that there are critical values in:
  - Surgical Pathology, 44/73 yes, 24 blank
  - Cytology, 31/57 yes, 22 blank
- Surgical Pathology – Call ASAP
  - Bacteria in heart or BM 91%
  - Organism in immune compromised patient 85%
- Cytology – Call ASAP
  - Bacteria or fungi in CSF 81% and 88%

Effective Communication of Important Results

- Arch Pathol Lab Med 2009;133:1375
- 1130 Laboratories surveyed
- 75% had AP “Critical Diagnosis” policy
- 52% of those with policy listed specific diagnoses
- Specific conditions included in the policy
  - All malignancies 48.3%
  - Life threatening infection 44.6%

Effective Communication of Important Results

- Arch Pathol Lab Med 2012;136:148-154
- Urgent diagnoses
  - Imminently life threatening
  - Very short list
  - Reported quickly
  - e.g. New infection in an immune compromised patient
- Significant unexpected diagnoses
  - Not imminently life threatening
  - Unusual or unexpected
  - Difficult to anticipate
  - Needs communication & documentation
  - e. g. carcinoma in biopsy taken for medical disease

Summary

- Source, frequency and significance of errors
- General principles of error reduction
- Identification errors (pre-analytic)
- Reasons for diagnostic (analytic) error
  - Clinical history and clinical correlation
  - Prospective and retrospective case reviews
- Post-analytic errors
  - Report completeness
  - Communication beyond the report

Thank You!

Questions?